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13 **IN THE UNITED STATES DISTRICT COURT**  
14 **FOR THE DISTRICT OF NEVADA**

15 **GLORIA JEAN ROGET**, Individually and  
16 As Special Administrator and Heir to the Estate  
of **ANDRE CARL ROGET**, Deceased,

17  
18 Plaintiff,

Case No.:

19 vs.

20 **MEDTRONIC, INC.**, a California  
21 Corporation, **MEDTRONIC MINIMED,**  
22 **INC.**, a Minnesota Corporation, and **DOES 1-**  
**20, ROE CORPORATIONS 1-20,**

23 Defendants.  
24

25 **PLAINTIFF'S ORIGINAL COMPLAINT FOR WRONGFUL DEATH,**  
26 **SURVIVAL ACTIONS AND JURY DEMAND**

27 COMES NOW Plaintiff, GLORIA JEAN ROGET, Individually (hereinafter "Plaintiff")  
28 and as Special Administrator and Heir to the Estate of ANDRE CARL ROGET, Deceased

(hereinafter “Decedent”), by and through the undersigned counsel, who brings this action for wrongful death pursuant to Section NRS 41.085 of the Nevada Rules of Civil Procedure, and come now Plaintiff who brings this survival action pursuant to NRS 41.130 of the Nevada Rules of Civil Procedure against Defendants, MEDTRONIC, INC., and MEDTRONIC MINIMED, INC., DOES 1-20 and ROES 1-20 (collectively “Defendants”). As grounds thereof, Plaintiff states the following:

### **INTRODUCTION**

1. This is a products liability action against Defendants for the failure of their medical device, prescribed to Decedent. The device was used by Decedent, and because of defects related to the device, Decedent suffered an insulin-induced coma that led to his eventual death on May 14, 2020.

2. This complaint alleges claims under parallel state law duties based on the Defendants’ failure to conform with the FDA’s Pre-Market Approval (PMA) process for this medical device and failure to conform and violations of FDA regulations.

3. The Decedent was a Type II diabetic and was prescribed the Defendants’ insulin infusion medical device – Medtronic’s MiniMed 630G insulin infusion pump - intended and used for the treatment of Type II diabetes mellitus. The Decedent then used the device that malfunctioned and put him in an insulin-induced coma causing his eventual death. Plaintiff and Decedent were informed and believed and thereon allege that these devices, were researched, designed, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, placed in the stream of commerce, and sold or otherwise provided to Decedent by Defendants, MEDTRONIC MINIMED, INC. and/or MEDTRONIC, INC. and/or DOES 1-20 and/or ROES 1-20.

**JURISDICTION AND VENUE**

4. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiff and Defendants. Defendants are either incorporated and/or have their principal place of businesses outside of the State of Nevada in which the Plaintiff resides.

5. The amount in controversy between Plaintiff and Defendants exceeds \$75,000, exclusive of interest and cost.

6. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

7. Venue is proper within this district pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and is subject to personal jurisdiction in this district. Furthermore, Defendants sell, market, and/or distribute insulin pumps within the District of Nevada. Also, a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

**PARTIES**

8. Plaintiff is an adult citizen and resident of Las Vegas, Clark County, Nevada.

9. Plaintiff is the surviving spouse and personal representative of Decedent's estate.

10. Plaintiff and Decedent were married on May 13, 1967, and remained married until Decedent's death.

11. The Decedent died on May 14, 2020, in Las Vegas, Clark County, Nevada.

12. At all times material hereto, Defendant, MEDTRONIC, INC., was and is a Foreign For-Profit Corporation (incorporated in Minnesota) which, at all times relevant to this lawsuit, was authorized to do business in the State of Nevada, and which operated, conducted, engaged in, and/or carried on a business or business venture throughout the State of Nevada for

1 which it received substantial revenue. Its principal place of business is located at 710 Medtronic  
2 Parkway, Minneapolis, Minnesota 55432. This defendant may be served via its Registered  
3 Agent: **Corporation Service Company, 112 North Curry Street, Carson City, Nevada**  
4 **89703.**

5  
6 13. At all times material hereto, Defendant, MEDTRONIC MINIMED, INC., was  
7 and is a Foreign For-Profit Corporation (incorporated in Delaware) which was doing business  
8 throughout the State of Nevada for which it received substantial revenue. Its principal place of  
9 business is located at 18000 Devonshire Street, Northridge, California 91325. This Defendant  
10 may be served via its Registered Agent: **Corporation Service Company, 251 Little Falls**  
11 **Drive, Wilmington, DE 19808.**

12  
13 14. Plaintiff does not know the true names and identities of those Defendants  
14 designated as DOES I through 20, ROES I through 20 inclusive, but alleges that each of said  
15 fictitiously named Defendants was negligently and unlawfully responsible for the events herein  
16 described, and for the injuries and damages sustained by Plaintiff and Decedent. Plaintiff will  
17 ask leave of court to amend this complaint when the identity of each such fictitiously named  
18 Defendant has been ascertained.

19  
20 15. Decedent's injuries, including death, proximately resulted from the wrongful,  
21 reckless, and negligent acts and omissions, and fraudulent misrepresentations of Defendants  
22 and/or each of them, all of which occurred within the venue of this court.

23  
24 16. At all times relevant to this action, the term "Defendants" includes all Defendants  
25 unless otherwise noted, including but not limited to MEDTRONIC MINIMED, INC.,  
26 MEDTRONIC, INC., DOES 1 through 20, and ROES 1 through 20, inclusive.

27 ///



1 or contribute to the death or serious injury, if the malfunction were  
2 to recur...

3 20. In contravention of applicable federal regulations, Medtronic has failed to report  
4 an incident involving a MiniMed insulin pump in which “device failure or malfunction may  
5 have contributed to or caused the user’s hospitalization and the device’s malfunction would be  
6 likely to cause or contribute to a death or serious injury, if the malfunction were to recur.”

7  
8 21. The FDA also found fault with the personnel that Medtronic entrusted at its  
9 manufacturing facility in Puerto Rico when determining whether a Medtronic device was  
10 dangerous. Specifically, the FDA cited Medtronic for:

11 Failure to have a person who is qualified to make a medical  
12 judgment reasonably conclude that a device did not cause or  
13 contribute to a death or serious injury, or that a malfunction would  
14 not be likely to cause or contribute to a death or serious injury, if it  
15 were to recur, as required by [United States Federal Law.]  
16 Personnel qualified to make a medical judgment include  
17 physicians, nurses, risk managers and biomedical engineers under  
18 [United States Federal Law.]

19 22. According to FDA Investigators, this plant had a wide range of problems that  
20 included lax testing of products for defects, improper record-keeping, and employing someone  
21 with insufficient training as a medical expert to determine danger or defects. Said employee  
22 only had a high school diploma with some additional in-house training. In listing these and  
23 other violations, the FDA concluded that the problems may be symptomatic of serious problems  
24 in Medtronic’s manufacturing process and its quality controls.

25 23. None of the cited violations reflect Medtronic’s promise to strive “without  
26 reserve for the greatest possible reliability and quality in our products; to be the unsurpassed  
27 standard of dedication, honesty, integrity, and service.”

28 ///

1           24.     On or about June 29, 2009, these issues led to a Class 1 recall of many of the  
2 Defendants' insulin infusion sets labeled Paradigm Quick-Set Infusion Sets. Said recall included  
3 lots manufactured between 2007 and 2009. Approximately three million disposable infusion  
4 sets were recalled.

5  
6           25.     On or about June 7, 2013, Medtronic MiniMed Paradigm infusions sets were  
7 recalled via a Class 1 recall. The recall was issued "because of a potential safety issue that can  
8 occur if insulin or other fluids come in contact with the inside of the tubing connector. If this  
9 occurs, it can temporarily block the vents that allow the pump to properly prime."

10  
11           26.     The 2013 recall admitted that "[t]his can result in too much or too little being  
12 delivered resulting in hypoglycemia or hyperglycemia which can be severe and lead to serious  
13 illness."

14           27.     The 2013 recall was virtually identical to the 2017 recall with regard to the  
15 infusion set at issue in this case. The same problems fluid causing a vent blockage resulting in  
16 the same outcomes over-delivery of insulin are at issue in both recalls.

17  
18           28.     It is clear that Medtronic did not resolve the problem with their product which  
19 resulted in the 2013 recall. Medtronic marketed the subject infusion sets without fixing the  
20 problem, resulting in another recall for the same defect in 2017.

21           29.     Unfortunately, non-conformance with FDA's approval and regulations, including  
22 past recalls and problems associated with Medtronic infusion sets did not result in Medtronic  
23 putting safer products into the stream of commerce for use by Andre Carl Roget.

24  
25                   **THE CURRENT RECALL**

26           30.     On September 7, 2017, Medtronic issued an "Urgent Medical Device Recall"  
27 regarding Medtronic MiniMed Infusion Sets.

1           31. The Recall Notice states that “Medtronic has become aware of recent report of  
2 potential over-delivery of insulin shortly after an infusion set change.” Medtronic further notes  
3 that it has received reports of hypoglycemia requiring medical attention related to this issue,  
4 which Medtronic concedes can result in “hypoglycemia and in extreme cases, death.”  
5

6           32. The Recall Notice states that this problem is caused by fluid blocking the  
7 infusion set membrane during the priming/fill tubing process, which prevents the infusion set  
8 from working properly. The result can be fast delivery of multiple days’ worth of insulin.  
9

10           33. The Recall Notice also announces that Medtronic has an alternate infusion set  
11 design, which contains a “new and enhanced membrane material that significantly reduces the  
12 risk.”

13           34. As a result of the defective MiniMed Infusion Sets, Decedent received a large  
14 quantity of insulin, which resulted in severe hypoglycemia, diabetic coma, and his death on  
15 May 14, 2020.  
16

17           35. On November 21, 2019, Medtronic issued an “Urgent Field Safety Notification”  
18 to patients warning them of the potential risk of hyperglycemia (high blood glucose) or  
19 hypoglycemia (low blood glucose) associated with broken or missing pump retainer rings on the  
20 630G and 670G model insulin infusion pumps. Exhibit 1. The retainer ring enables the insulin-  
21 containing reservoir to be locked into place. Medtronic alerted patients to “reported incidents of  
22 a loose reservoir that can no longer be locked into the pump . . . due to a broken or missing  
23 retainer ring that prevents a proper lock.” *Id.* The Field Safety Notification continued:  
24

25           If the reservoir is not properly locked into the pump, it could lead to over or under  
26 delivery which could then result in hypoglycemia or hyperglycemia.

- 27           • For example, if the pump retainer ring is broken or  
28 becomes detached from the pump, and the user  
inserts the reservoir back into the pump while the



infusion set is still connected to the body, it could result in a rapid infusion of insulin, which could cause hypoglycemia. The under delivery of insulin could occur if the reservoir is not properly locked into place by the retainer ring, creating a space between the pump and the reservoir, and preventing the pump from pushing the expected insulin into the body, which could cause hyperglycemia. *Id.*

Medtronic instructed patients to discontinue using the pump and consult with their healthcare providers “if the reservoir does not lock into the pump or the retainer ring is loose, damaged or missing.” If, however, the reservoir “properly locks in place by the reservoir ring” patients were instructed to “continue to use your pump.”



The images show a **normal** pump retainer ring vs a **damaged or missing** pump retainer ring.



**Image:** Location of the retainer ring on the MiniMed™ 600 series insulin pump

36. Almost exactly 3 months later, on February 12, 2020, Medtronic issued a recall of more than 300,000 of their 630G and 670G insulin pumps in the U.S. Upon information and belief, this is the entire installed base of these models pumps in the U.S. It is also believed that more than 100,000 additional units outside of the U.S. were subject to the recall. The FDA

1 classified the recall as a Class I recall because it deemed the use of these devices under the  
2 circumstances "may cause serious injuries or death." Exhibit 2. The affected lots are those  
3 manufactured before October 2019 and distributed between September 2016 and October 2019  
4 (630G model) or manufactured before August 2019 and distributed between June 2017 and  
5 August 2019 (670G model). *Id.* The FDA reported that Medtronic had received a total of more  
6 than 26,400 complaints of which 2,175 reported injuries with one (1) known death. *Id.* This  
7 letter was sent on March 5, 2020. Exhibit 3.

9 37. Consistent with the Quality Systems Regulations, 21 C.F.R. § 820, which govern  
10 the manufacture of Class III pre-market approval ("PMA") medical devices, the November  
11 2019 "Urgent Field Safety Notification" which preceded the February 2020 Class I recall would  
12 have been the result of Medtronic initiating a "Corrective and Preventative Action" ("CAPA")  
13 process in response to complaints received from patients. That CAPA process would have been  
14 triggered when Medtronic detected a "safety signal" through post-marketing complaints about  
15 the device. As its name suggests, the purpose of the CAPA is to identify the cause of the  
16 problem and develop "corrective" measures for the problem and take "preventative" actions to  
17 make sure that non-conforming products do not make it to market. *See* 21 C.F.R. § 820.100. A  
18 foundational aspect of a CAPA is a "root cause analysis" to determine, among other things, if  
19 the problem is one of design, manufacturing, or potentially both.

## 22 THE PUMPS

### 23 **A. Model 630G**

24 38. The 630G is the successor to the 530G, Medtronic's first "artificial pancreas"  
25 approved in 2013. The 530G differed from all of its predecessors in that the real-time sensor  
26 values from the continuous glucose monitoring functions of the pump could directly interact  
27

1 with insulin delivery through the “threshold suspend feature” which could automatically  
2 suspend insulin delivery for up to two hours if sensor glucose values fell below a threshold and  
3 the patient failed to respond to alerts and alarms. Medtronic described the “major difference”  
4 between the 530G and 630G, which was approved for marketing on August 10, 2016, as an  
5 updated display screen that presented in color. The 630G used the same “threshold suspend”  
6 algorithm as the 530G.  
7

8 **B. Model 670G**

9 39. The 670G was approved for marketing six weeks after the 630G on September  
10 28, 2016, as an “Automated Insulin Delivery System,” which included an “Auto Mode” feature  
11 which could “automatically adjust basal insulin delivery using continuous glucose monitor data  
12 [and] automatically increase or decrease the amount of insulin delivered based on sensor  
13 values.” As described in the Summary of Safety and Efficacy Data (SSED), the 670G has an  
14 “Auto Mode,” a “new tool” that  
15

16 uses an algorithm to automatically adjust basal insulin delivery using continuous  
17 glucose monitor data. When in Auto Mode, the pump responds to fluctuations in  
18 interstitial fluid glucose levels measured by the continuous glucose monitor; the  
19 Auto Mode feature can automatically increase or decrease the amount of basal  
insulin delivered based on sensor glucose values.

20 The Auto Mode algorithm is designed to adjust the user's basal insulin rates to try  
21 to keep them at a target blood glucose level. The standard target glucose setting in  
22 Auto Mode is 120 mg/dL, and the target can also be set temporarily to 150 mg/dL  
23 for exercise and other events. In addition, blood glucose readings above 150  
24 mg/dL will prompt the Auto Mode feature to calculate if a correction bolus is  
25 needed; if needed, a correction bolus will be recommended to the users, who can  
choose whether they want to deliver that correction bolus. Users should check  
their blood glucose levels using a blood glucose meter before administering a  
correction bolus.

26 ///

27 ///

**STATEMENT OF DECEDENT'S FACTS**

40. Decedent was diagnosed as Type II diabetic in 1999. As a result, he was prescribed to use an insulin infusion pump which he used and would receive a new pump approximately every five (5) years.

41. In January 2019, Decedent received his new Medtronic MiniMed 630G insulin pump from the Defendants. Since January 2019, Decedent used the Medtronic MiniMed 630G Insulin Pump, serial number NG2135451H, until his hypoglycemic episode that resulted in going into a diabetic coma for seven days and ultimately dying on May 14, 2020.

42. Because of his diabetic condition, Decedent managed his diabetes through the use of insulin pump therapy, specifically; by using the Medtronic MiniMed 630G Insulin Pump to deliver the necessary amount of insulin into his bloodstream to properly treat his diabetes. When functioning correctly, these devices and their components mimic how a healthy pancreas works by delivering continuous and controlled doses of rapid-acting insulin, 24 hours a day, to match the user's body's needs.

43. On April 18, 2020, Decedent was at his home and went to bed early due to not Decedent feeling well. The Medtronic MiniMed 630G MMT-1755K Insulin Pump at issue was part of an FDA Class 1 Device Recall on November 21, 2019. Unfortunately, Plaintiff states that she does not remember receiving any notification of the recall, nor does she remember her husband receiving any notification of the recall. Thus, Decedent continued using his insulin pump.

44. On the morning of April 19, 2020, Plaintiff found her husband, Decedent, unconscious and unresponsive in their bedroom. Plaintiff called 9-1-1, and the paramedics arrived to treat Decedent.

1           45.     The Decedent was rushed by ambulance to SHM – Summerlin Hospital Medical  
2 Center in Las Vegas, Nevada, where it was determined that he was suffering from profound  
3 hypoglycemia due to his insulin pump.

4           46.     The collective Defendants, along with their agents and employees, negligently  
5 caused the defective insulin pumps to be designed, manufactured, assembled, distributed, and  
6 sold to members of the public, and they further negligently failed to remove the recalled  
7 infusion sets from the marketplace and stream of commerce after they had knowledge of the  
8 defects as well as the recall.

9           47.     The Defendants designed, manufactured, marketed, and distributed the  
10 Medtronic MiniMed 630G Insulin Pump and Pro Set Infusion Sets, which were marketed to  
11 deliver insulin to a person with diabetes in measured amounts. The MiniMed pump was  
12 manufactured with a retainer ring designed to lock the patient's insulin cartridge into place in  
13 the pump's reservoir compartment. Pro Set Infusion Sets consist of a membrane and disposable  
14 plastic tubes which transport insulin from the pump to the patient's body. The Medtronic  
15 MiniMed 630G Insulin Pump and Pro Set Infusion Sets are used in conjunction with one  
16 another to help people with diabetes regulate their blood sugar by providing a constant source of  
17 insulin. They provide an alternative to daily injections of insulin. The pump connects to flexible  
18 plastic tubing that delivers insulin to the body. Users set the pump to deliver insulin throughout  
19 the day. It can be programmed to release larger doses at meals or when blood sugar levels are  
20 too high.

21           48.     Plaintiff, nor the Decedent, had any way of knowing that the Medtronic  
22 MiniMed 630G Insulin Pump and Pro Set Infusion Sets that he used on the night of the incident  
23 were defective in design, manufacture, and marketing, and that, even when used in conformance  
24

1 with Defendants' instructions, were prone to deliver doses of insulin incorrectly and in life-  
2 threatening doses.

3 **CAUSES OF ACTION**

4 **FIRST CAUSE OF ACTION**  
5 **STRICT PRODUCT LIABILITY**

6 (Against all Defendants, Does 1-20 and Roes 1-20)

7 49. The Plaintiff and Decedent incorporate by reference and reallege each and every  
8 allegation in this Complaint the same as though specifically set forth herein.

9 50. Plaintiff and Decedent hereby assert a strict liability claim for defective  
10 manufacturing pursuant to applicable Nevada law.

11 51. Each of the Defendants are medical device companies engaged in the design  
12 and/or research and/or manufacture and/or production and/or testing and/or assembling and/or  
13 labeling and/or packaging and/or distribution and/or sale and/or otherwise involved in placing  
14 various medical devices into the stream of commerce, intended human use including facilitating  
15 the infusion and/or ingestion of drug products such as insulin for diabetes control.  
16

17 52. At the times and places mentioned above and at all times material thereto, each  
18 of the Defendants, held themselves out as knowledgeable and possessing the requisite skill  
19 particular to the research and/or manufacture and/or production and/or testing and/or  
20 assembling and/or labeling and/or packaging and/or distribution and/or sale of such products.  
21

22 53. At the times and places aforesaid, and at all times material hereto, Defendants,  
23 and each of them, placed into the stream of commerce medical devices which were  
24 unreasonably dangerous through defective manufacture and/or which failed to conform to the  
25 specifications approved by the FDA and/or failed to function as intended and/or malfunctioned  
26 and were therefore not safe and effective, and were unfit for their intended purpose and  
27  
28

1 foreseeable uses and were in a defective and dangerous condition in violation of the approvals  
2 received by the FDA, and the requirements thereunder.

3 54. Defendants, and each of them, caused or otherwise allowed, enabled or  
4 facilitated the placement of unreasonably dangerous products in a defective condition, and in  
5 violation of the FDA's requirements, into the stream of commerce, and are strictly liable in tort.  
6

7 55. As a foreseeable, direct, and proximate result of the direct and proximate cause  
8 of the manufacturing defects and the Defendants' conduct alleged herein, Decedent sustained  
9 injuries and damages, including his death for which a cause of action is hereby stated.

10  
11 **SECOND CAUSE OF ACTION**  
12 **NEGLIGENCE**

(Against all Defendants, Does 1-20 and Roes 1-20)

13 56. The Plaintiff and Decedent incorporate, adopts by reference, and reallege each  
14 and every allegation of this Complaint the same as though specifically set out herein again.

15 57. At all times relevant to this Complaint, Defendants had a duty to assure that  
16 those products that they placed into the stream of commerce were free of defects and reasonably  
17 fit and suitable for their intended or foreseeable uses and conformed to the FDA-approved  
18 specifications.  
19

20 58. At all relevant times material hereto, Defendants, and each of them, placed or  
21 caused to be placed into the stream of commerce, a product or products which were in a  
22 defective and unreasonably dangerous condition, not in conformance with FDA-approved  
23 specification and/or not reasonably fit or suitable for their intended or foreseeable uses or  
24 otherwise not conforming with specifications.  
25

26 59. Defendants and each of them knew or should have known in the exercise of  
27 reasonable care that their MiniMed products were defective and in a dangerous condition and/or  
28

1 not reasonably fit or suitable for their intended or foreseeable purpose uses and negligently  
2 placed these non-conforming and defective products into the stream of commerce where they  
3 would be expected to be utilized by insulin-dependent diabetics like Decedent.

4  
5 60. Injuries and damages sustained by the Decedent, including his death, were both  
6 proximately caused and a reasonably foreseeable result of Defendants' products and conduct.

7 61. As a foreseeable, direct, and proximate result of Defendants' negligence,  
8 Decedent and Plaintiff and each of them was injured, with Decedent suffering bodily injury,  
9 harm, and ultimately his death, and both Plaintiff and Decedent sustained damages compensable  
10 under Nevada law.

11  
12 **THIRD CAUSE OF ACTION**  
13 **BREACH OF EXPRESS WARRANTY**  
(Against all Defendants, Does 1-20 and Roes 1-20)

14 62. The Plaintiff and Decedent incorporate by reference and reallege each and every  
15 allegation in this Complaint the same as though specifically set forth herein.

16  
17 63. At all relevant times, Defendants expressly represented and warranted through  
18 written literature, including but not limited to product labeling, patient package inserts, articles  
19 in medical journals, advertising, and other documentation and/or promotional materials directed  
20 to Decedent's physician, and/or the Decedent and Plaintiff, by and through Defendants'  
21 authorized agents or sales representatives orally and in writing that the Medtronic MiniMed  
22 Infusion Sets and MiniMed 630G Insulin Pump were safe and free from defects, effective, and  
23 fit and proper for their intended use or foreseeable uses in accordance with and conformed to  
24 FDA regulations and specifications. Said representations were in the form of marketing  
25 materials, device information, and product materials provided to Andre Roget, Decedent.  
26 Decedent justifiably relied on said representations and express warranties in electing to use said  
27  
28



1 product.

2 64. For example, on its webpage, Medtronic touts that it is “delivering on our  
3 promises through medical innovation” and invited viewers to “discover our full breadth of  
4 reliable, safe, high-quality devices.” Following the hyperlink “Browse Our Products” leads to a  
5 page in which additional links for the 630G and 670G are available. Clicking on the 630G link  
6 leads to a promotional brochure captioned “Better Control, Fewer Lows. Making it easier for  
7 patients to manage their diabetes – so they can live exceptional lives.”  
8

9 65. On Page 4 of the Medtronic brochure, Medtronic touts that “93% of patients who  
10 use SmartGuard technology [incorporated in the closed loop system] say they feel more secure  
11 and confident in treating their diabetes” The source of this data can be found two pages later  
12 embedded in a dense footnote in very small type and is drawn from “user evaluations” with the  
13 “data on file [at] Medtronic MiniMed.” This is potentially misleading because it suggests that  
14 93% of all users, rather than just the users who completed the evaluations feel more secure and  
15 confident.  
16

17 66. Similarly, a promotional brochure for patients promises “Freedom” through  
18 “breakthrough diabetes technology that lets you focus more on living your life.” The device is  
19 described as representing “revolutionary technology [that] automatically adjusts to your life. On  
20 page 6 of the brochure in a footnote in small print, the “revolutionary technology” is noted to  
21 refer to the “SmartGuard Auto Mode feature” which “can automatically increase or decrease  
22 insulin delivery based on continuous glucose monitoring (CGM) values.”  
23

24 67. The Decedent was prescribed and/or purchased and/or consumed and/or  
25 otherwise utilized the Defendants’ devices for the purposes of controlling his blood glucose  
26 levels by way of an insulin pump and associated equipment. In so doing, Decedent relied upon  
27  
28

1 the skill, judgment, representations, and foregoing express written warranties of the Defendants.  
2 Said warranties and representations were false, misleading, and inaccurate in that the  
3 aforementioned product was defective and/or not in compliance with FDA regulations and/or  
4 did not conform to or perform in accordance with approved specifications and/or malfunctioned  
5 or failed to perform as intended during use and was not therefore safe and effective and was  
6 unfit for the uses for which it was intended or put with the knowledge and/or encouragement  
7 and/or approval of Defendants.  
8

9 68. The Medtronic MiniMed Infusion Sets and MiniMed 630G Insulin Pump at issue  
10 did not conform to the Defendants' express representations and warranties.  
11

12 69. At all relevant times, said products did not perform as safely as an ordinary  
13 consumer would expect when used as intended or in a reasonably foreseeable manner.

14 70. At all relevant times, said products did not perform in accordance with the  
15 Defendants' representations.

16 71. As a direct and proximate consequence of the breach of express warranties by  
17 the Defendants, and each of them, Decedent after purchasing and/or consuming and/or ingesting  
18 and/or otherwise utilizing Defendants non-conforming and defective medical device, suffered  
19 injuries, sustained damages, and that ultimately led to his death all compensable under Nevada  
20 law. Decedent, and Plaintiff, who suffered injuries compensable under Nevada law due to the  
21 death of Decedent, hereby assert a claim for breach of express warranty pursuant to applicable  
22 Nevada law.  
23

24  
25 ///

26 ///

27 ///

**FOURTH CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTY**  
(Against all Defendants, Does 1-20 and Roes 1-20)

72. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

73. At all times and places material hereto, Defendants, and each of them, impliedly warranted to Decedent and/or Decedent's physicians that said products were of merchantable quality, were manufactured and/or packaged and/or labeled in accordance with FDA regulations, complied with applicable FDA regulations and approved specifications and were safe, effective and fit for use for which they were intended or for other known or foreseeable uses.

74. Decedent and Plaintiff were unskilled in the research, design, and manufacture of the product and reasonably relied entirely on the skill, judgment and implied warranties of Defendants, and each of them, in being prescribed, purchasing, consuming, and otherwise using the 630G and accompanying devices.

75. The 630G was not designed and/or manufactured and/or packaged and/or labeled in accordance with FDA regulations, did not conform to or perform in accordance with approved specifications, and/or was otherwise defective and was not therefore not safe or effective for its intended, known or foreseeable uses not of merchantable quality, as warranted by Defendants in that they had the potential to malfunction and/or fail to function as intended and cause serious and permanent injuries, including death when used for their intended, known, and foreseeable uses.

76. As a result of the aforementioned breach of implied warranties by Defendants, Decedent and Plaintiff, after Decedent being prescribed and/or after purchasing and/or

1 consuming and/or otherwise using Defendants' non-conforming, defective products, suffered  
2 injuries and sustained damages compensable under the laws of the State of Nevada.

3 77. The Defendants' breaches of implied warranties, pursuant to Nevada law,  
4 proximately resulted in the damages sustained by the Decedent, including his death.  
5

6 **FIFTH CAUSE OF ACTION**  
7 **CONSUMER PROTECTION**

(Against all Defendants, Does 1-20 and Roes 1-20)

8 78. The Plaintiff and Decedent incorporate by reference and reallege each and every  
9 allegation in this Complaint the same as though specifically set forth herein.  
10

11 79. Defendants are the researchers, developers, manufacturers, distributors,  
12 marketers, promoters, suppliers, and sellers of the 630G insulin infusion pump, and  
13 accompanying devices, which Defendants represented to be free from defects and fit for their  
14 intended or foreseeable purposes in conformance with FDA approvals and regulations.

15 80. Defendants advertised, labeled, marketed, and promoted their products,  
16 representing the quality to healthcare professionals, the FDA, Decedent, Decedent's treating  
17 physicians, and the public in such a way as to induce the product's purchase or use.  
18

19 81. Defendants knew or should have known that their products did not or would not  
20 conform to Defendants' representations and promises because the product was defective.

21 82. Defendants concealed knowledge of the serious risks associated with the device,  
22 concealed testing and research data, or selectively and misleadingly revealed or analyzed testing  
23 and research data, and concealed the fact that the devices were defective.  
24

25 83. Defendants' representations, actions, and conduct regarding their devices were in  
26 or affecting commerce and were misleading.

27 ///

84. Defendants' actions and conduct, as alleged throughout this Complaint, constitute deceptive trade practices under Nevada Revised Statutes, Title 52, Chapter 598 et seq. and/or other applicable statutory provisions concerning deceptive trade practices or consumer fraud.

85. As a direct and proximate result of Defendants' deceptive and/or unfair conduct, in affecting commerce, Decedent and Plaintiff are entitled to recover damages from Defendants, pursuant to the provisions of the Nevada Deceptive Trade Practices Act ("NDTPA"), codified as NRS Chapter 598 et seq. and/or other applicable statutory provisions concerning deceptive trade practices and consumer fraud.

**SIXTH CAUSE OF ACTION  
SURVIVAL ACTION**

(Against all Defendants, Does 1-20 and Roes 1-20)

86. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

87. Plaintiff brings a survival action for any and all losses or damages which accrued as a result of Defendants' non-conforming products prior to Decedent's death. Including, all causes of action alleged herein, punitive and exemplary damages, damages for pain and suffering, loss of probable support and companionship, society, comfort, and consortium.

**SEVENTH CAUSE OF ACTION  
WRONGFUL DEATH – NRS 41.085**

(Against all Defendants, Does 1-20 and Roes 1-20)

88. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

89. As alleged herein the Defendants' non-conforming product, the 630G MiniMed, and accompanying products wrongfully caused the death of the Decedent.

1           90. As a result of the aforementioned breaches and wrongful conduct by Defendants,  
 2 and after Decedent being prescribed and/or after purchasing and/or consuming and/or otherwise  
 3 using Defendants' non-conforming, defective products, suffered injuries and sustained damages  
 4 and led to his death, all of which are compensable under the laws of the State of Nevada.  
 5

6                           **DAMAGES AS TO ALL CAUSES OF ACTION**

7           91. Plaintiff and Decedent were injured as a direct and proximate result of the  
 8 conduct and breaches of the Defendants, as aforesaid, for which compensation is required.  
 9 Specifically, the Defendants' products caused the Decedent to experience extreme  
 10 hypoglycemia, diabetic coma, and ultimately his death. Plaintiff, on behalf of Decedent and  
 11 herself is seeking monetary damages in the form of:  
 12

- 13                   a. Damages for past medical, hospital and drug bills for Decedent;
- 14                   b. Damages companionship, society, comfort and consortium;
- 15                   c. Damages for disfigurement, impairment and/or disability;
- 16                   d. Damages for past and future mental anguish, grief or sorrow and  
 17 emotional distress for Plaintiff;
- 18                   e. Damages for loss of enjoyment of life;
- 19                   f. Damages for all other losses, both economic and intangible, arising from  
 20 the injuries as set out herein, all of which were proximately caused by the  
 21 act/or omissions of the Defendants;
- 22                   g. Punitive and exemplary damages; and
- 23                   h. Any other relief which the Court deems just and proper under the  
 24 circumstances.

25           92. Plaintiff reserves the right to prove the amount of damages at trial, in an amount  
 26 to be determined by the jury.

27       ///



1 Plaintiff, GLORIA JEAN ROGET, Individually and as Special Administrator and Heir  
2 to the Estate of ANDRE CARL ROGET, Deceased:

- 3 1. For DECEDENT's medical and related expenses according to proof;
- 4 2. For PLAINTIFF's loss of income and income potential caused by DECEDENT's  
5 death, and for PLAINTIFF's loss of DECEDENT's financial support and  
6 financial contributions;
- 7 3. For damages for fraud according to proof;
- 8 4. For funeral and burial expenses caused by DECEDENT's death;
- 9 5. For PLAINTIFF's general damages according to proof, including damages for  
10 loss of love, companionship, comfort, affection, solace, moral support and/or  
11 society according to proof caused by DECEDENT's death;
- 12 6. For exemplary or punitive damages according to proof;

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8. For such other and further relief as the Court may deem just and proper, including costs.

**HENNESS & HAIGHT INJURY LAW**

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